5. 510(k) Summary

Trade Name:	Modified Concentric Microcatheter
Common Name:	Diagnostic Intravascular Catheter
Classification Name:	Diagnostic Intravascular Catheter, 21CFR 870.1200 - Class II
Product Code:	DQO, DQY and KRA
Submitter:	Concentric Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-237-5230 Facility Registration #2954917
Contact:	Christina Rowe Manager, Regulatory Affairs
Date Prepared:	September 6, 2013
Predicate Device:	Concentric Microcatheter (K113260)

OCT 11 2013

Device Description

The Modified Concentric Microcatheter is a line extension to the existing Concentric Microcatheter, cleared under K113260. Like the predicate device, the Modified Concentric Microcather is a single-lumen, braided shaft, variable stiffness catheter designed for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures. A luer hub on the proximal end of the shaft enables connection to the rotating hemostasis valve included in the package. The radiopaque shaft and distal marker facilitate fluoroscopic visualization. The catheter shaft is coated with a hydrophilic coating to reduce friction during use. The Modified Concentric Microcatheter differs from its predicate in that it has smaller shaft diameters and a longer effective shaft length. Device dimensions and configuration are shown on the product label. A rotating hemostasis valve with side-arm adapter is provided with each microcatheter.

Indications for Use

The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

Technological Characteristics

The Modified Concentric Microcatheter has the same technological characteristics as compared to the predicate device (K113260). The Modified Concentric Microcatheter differs from the predicate device in that its shaft diameters are smaller and its effective shaft length is longer. The device design, materials used, function, physical properties and composition have not been changed. A comparison of the subject device with predicate device is summarized in the table below.

Product Feature Comparison of Subject Device with Predicate Device

Feature	**Results**
Indications for Use	Same
Device Description	Same except smaller shaft diameters and longer effective shaft length
Target Population	Same
Accessory Devices Provided	Same
Materials	Same
Labeled shaft outer diameter	Smaller (2.4F vs. 2.7F)
Labeled shaft inner diameter	Smaller (.017" vs. .021")
Overall Length	Longer (157 cm vs. 150 cm)
Packaging Materials and Configuration	Same
Sterilization Method	Same
How Supplied	Same

Testing Summary

The results of verification and validation conducted on the Modified Concentric Microcatheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. The test methods applied were similar to those previously submitted for the predicate Concentric Microcatheter.

Specifically, the following tests were performed on the proposed device:

Design verification testing:

- Kink Resistance – the device's ability to withstand kinking when flexed was successfully evaluated.
- Leak Resistance – the device's leak resistance when subjected to both high pressure and vacuum was successfully evaluated.
- Flexibility Testing – the device's ability to navigate tight bends was successfully evaluated.
- Tensile Testing – the device's mechanical integrity under tensile loads was successfully evaluated.
- Torque Testing – the device's mechanical integrity when subjected to torsion was successfully evaluated.
- Coating Testing – the durability and lubricity of the device coating was successfully evaluated.

In addition, dimensional verification testing was performed as part of design verification tests for the proposed device.

Design validation testing:

- Radiopacity Testing – the visibility of the device under fluoroscopy was successfully evaluated.
- Design Validation Simulated Use Testing – testing was performed in a porcine model to confirm that the proposed device meets its intended use.

The Modified Concentric Microcatheter uses the same materials and processes as the predicate device. Biocompatibility and sterilization tests were performed on the predicate device; results for all tests met the pre-determined acceptance criteria and apply to the Modified Concentric Microcatheter.

Summary of Substantial Equivalence

The Modified Concentric Microcatheter is substantially equivalent to the predicate device with regard to device design, materials, intended use, and patient population. The results of verification and validation conducted on the Modified Concentric Microcatheter demonstrate that it performs as designed, is suitable for its intended use and is as safe, as effective, and performs as well as or better than the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

Concentric Medical, Inc.
c/o Ms. Christina Rowe
Manager, Regulatory Affairs
301 E. Evelyn Ave.
Mountain View, CA 94041

Re: K131437
Trade/Device Name: Modified Concentric Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, DQY and KRA
Dated: September 9, 2013
Received: September 10, 2013

Dear Ms. Rowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131437

Device Name: Modified Concentric Microcatheter

Indications For Use: The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S